

Clinical and Epidemiological Profile of Insulin Analog Users: Temporal Population-based Analysis

Perfil Clínico e Epidemiológico de Usuários de Análogos de Insulina: Análise Populacional Temporal
Perfil Clínico y Epidemiológico de Usuarios de Análogos de Insulina: Análisis Poblacional Temporal

RESUMO

Objetivo: Analisar o perfil epidemiológico, territorial, antropométrico e terapêutico de usuários com diabetes mellitus tipo 1 em uso de análogos de insulina no Componente Especializado da Assistência Farmacêutica da Paraíba entre 2022 e 2025. **Método:** Estudo observacional, transversal e retrospectivo, com dados secundários de dispensação de análogos de insulina. Análise descritiva de variáveis demográficas, territoriais, antropométricas e terapêuticas. **Resultado:** Observou-se crescimento contínuo no número de pacientes e na dispensação de análogos, com maior expansão das insulinas de ação prolongada. A maioria era adulta, com distribuição estável por sexo e concentração nos centros urbanos. Em 2025 predominou o esquema basal-bolus, e usuários em esquema basal isolado apresentaram maior idade e sobrepeso e obesidade. **Conclusão:** O uso de análogos de insulina na rede pública de saúde da Paraíba mostrou crescimento progressivo, alinhado às diretrizes clínicas, contribuindo para o planejamento farmacêutico regional e o cuidado às pessoas com diabetes mellitus tipo 1.

DESCRIPTORES: Diabetes Mellitus; Insulina de Ação Prolongada; Assistência Farmacêutica; Sistema Único de Saúde; Acessibilidade aos Serviços de Saúde.

ABSTRACT

Objective: To analyze the epidemiological, territorial, anthropometric, and therapeutic profile of users with type 1 diabetes mellitus using insulin analogues within the Specialized Component of Pharmaceutical Services in Paraíba, Brazil, between 2022 and 2025. **Method:** Observational, cross-sectional, and retrospective study based on secondary data on insulin analogue dispensing. Descriptive analysis of demographic, territorial, anthropometric, and therapeutic variables was performed. **Results:** A continuous increase was observed in the number of patients and in insulin analogue dispensing, with greater expansion of long-acting insulins. Most users were adults, with stable sex distribution and concentration in urban centers. In 2025, the basal-bolus regimen predominated, and users on basal insulin alone had higher mean age and greater overweight and obesity. **Conclusion:** The use of insulin analogues in Paraíba's public health network showed progressive growth, aligned with current clinical guidelines, contributing to regional pharmaceutical planning and to the care of people with type 1 diabetes mellitus.

DESCRIPTORS: Diabetes Mellitus, Type 1; Long-Acting Insulin; Pharmaceutical Services; Unified Health System; Health Services Accessibility.

RESUMEN

Objetivo: Analizar el perfil epidemiológico, territorial, antropométrico y terapéutico de usuarios con diabetes mellitus tipo 1 en uso de análogos de insulina en el Componente Especializado de la Asistencia Farmacéutica en Paraíba, Brasil, entre 2022 y 2025. **Método:** Estudio observacional, transversal y retrospectivo, con datos secundarios de dispensación de análogos de insulina. Análisis descriptivo de variables demográficas, territoriales, antropométricas y terapéuticas. **Resultado:** Se observó crecimiento continuo en pacientes y en la dispensación de análogos, con mayor expansión de insulinas de acción prolongada. La mayoría eran adultos, con distribución estable por sexo y concentración en centros urbanos. En 2025 predominó el esquema basal-bolus; usuarios en esquema basal aislado presentaron

mayor edad y sobrepeso. **Conclusión:** El uso de análogos de insulina en la red pública de Paraíba mostró crecimiento progresivo, alineado con las directrices clínicas, y contribuye a la planificación farmacéutica regional y al cuidado de personas con diabetes mellitus tipo 1.

DESCRIPTORES: Diabetes Mellitus Tipo 1; Insulina de Acción Prolongada; Servicios Farmacéuticos; Sistema Único de Salud; Accesibilidad a los Servicios de Salud.

RECEIVED: 04/22/2026 **APPROVED:** 07/03/2026

How to cite this article: Pessoa LD, Neves MCM, Ribeiro VS, Souza TT, Faheina WB, Reis WCT, Melchiors AC. Clinical and Epidemiological Profile of Insulin Analog Users: Temporal Population-based Analysis. *Saúde Coletiva (Brazilian Edition)* [Internet]. 2026 [cited year month day];18 (113):21124-21143. Available from: DOI: 10.36489/saudecoletiva.2026v18i113p21124-21143



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INTRODUCTION

Type 1 diabetes mellitus (T1DM) is a disease characterized by the progressive loss of pancreatic β -cell function, resulting in absolute insulin deficiency. As a result of this pathophysiological mechanism, exogenous insulin administration is essential not only for sustaining life but also for preventing acute complications, such as diabetic ketoac-

idosis and coma, as well as chronic microvascular and macrovascular complications. Within the Unified Health System (SUS), access to rapid-acting insulin analogs (RAIA) and long-acting insulin analogs (LAIA) is managed through the Specialized Pharmaceutical Care Component (CEAF), with these technologies having been incorporated into the SUS in 2017 (RAIA) and 2019 (LAIA). This access pathway ensures that the

supply of these medications occurs in an organized and technically sound manner, and is strictly linked to compliance with the criteria established in the clinical protocol and therapeutic guidelines (PCDT) for type 1 diabetes¹⁻⁶.

According to the Clinical Protocol and Therapeutic Guidelines (PCDT) for type 1 diabetes mellitus, access to insulin analogs through the SUS is indicated for patients with a confirmed

diagnosis who exhibit inadequate glycemic control or recurrent episodes of hypoglycemia while using human insulin, subject to regular clinical monitoring and evidence of therapeutic benefit.⁷

The CEAf follows an organizational structure and system of responsibilities regarding drug treatments through a division into groups. In this context, Group 1A stands out, as it includes drugs whose procurement is centralized by the Ministry of Health due to their strategic importance or significant financial impact. This group includes insulin analogs, which are essential for the advanced management of diabetes mellitus. The inclusion of these medications in Group 1A ensures that their supply to the State and Federal District Health Departments occurs in a standardized manner throughout the country. Thus, while the federal government ensures centralized procurement, state agencies are responsible for managing scheduling, storage, and direct dispensing to users, thereby consolidating a continuum of care that seeks to optimize glycemic control and the quality of life for users of the SUS⁸.

Given this context, the present study aimed to analyze the epidemiological, geographic, anthropometric, and therapeutic profiles of patients with type 1 diabetes mellitus using insulin analogs who were served by the Specialized Pharmaceutical Care Component in the state of Paraíba from 2022 to 2025, describing the temporal evolution of dispensing, the insulin therapy regimens adopted, the demographic and nutritional characteristics of the patients, and their geographic distribution.

METHODS

Study Design

This is an observational, cross-sectional, and retrospective study based on secondary data, conducted us-

ing administrative records from the HÓRUS – Specialized system, developed to improve the management of the CEAf by enabling all stages of its implementation to be carried out electronically in the state of Paraíba from January 2022 to December 2025.

Data Source

The data were extracted from the National Pharmaceutical Care Management System (HÓRUS-Specialized), used by the Paraíba State Department of Health to manage CEAf requests, authorizations, and medication dispensing⁹

Ethical Considerations

This study was conducted in accordance with current ethical guidelines and was submitted to and approved by the Research Ethics Committee of the Paraíba School of Public Health (CEP/ESP-PB). Approval was Formalized under Opinion No. 7,936,555, issued on October 30, 2025, under the Certificate of Submission for Ethical Review (CAAE) No. 90650325.6.0000.5186. Because secondary and anonymized databases were used, the requirement for Informed Consent (TCLE) was waived.

Study Population

The study population consisted of all registered and authorized users in the HÓRUS-Especializado system in Paraíba. Users included in the study were those with an active record in the system with an approved request, who had at least one dispensing of an insulin analog during the analyzed period, and who had minimum available information for profile characterization, such as sex, age, weight, and height. Records with missing or inconsistent information on essential variables, those related to canceled or unfulfilled dispensing requests, as well as users with inactive status in the system, were excluded from the

analysis to ensure greater reliability and consistency of the data used in the study. Top of the form Bottom of the form

Data Processing and Analysis

The data were exported from the HÓRUS system in electronic format and cleaned for subsequent standardization and consolidation, including:

- Identification and removal of duplicates;
- Checking for inconsistencies;
- Standardization of categories and codes.

Microsoft Excel 2025 was used for the organization, tabulation, and descriptive analysis of the collected data. The software's logical functions and pivot tables were used to process the variables. Statistical analysis was performed using **Microsoft Excel**, including descriptive analysis of the data, with calculations of absolute and relative frequencies for the categorical variables, as well as measures of central tendency and dispersion (mean, median, and standard deviation) for the numerical variables¹⁰

RESULTS

Trend in the total number of patients over time

The temporal analysis showed a progressive and continuous increase in the total number of patients treated between 2022 and 2025. Over the entire period, there was a total increase of 48.3%, rising from 4,203 patients in the first year to 6,233 by the end of 2025, as shown in the following figure:

Figure 1 – Temporal evolution of the number of patients, Paraíba, 2022–2025.



Source: The authors—2026

Trend in the Number of Patients

Between 2022 and 2025, there was a steady increase in the dispensing of insulin analogs at CEAF, totaling 593,224 units during that period. The increase was more pronounced for long-acting analogs, whose dispensing grew

by 102.8%, while rapid-acting analogs increased by 48.3%. This highlights greater expansion of basal insulin-based regimens, as shown in the following figure, which lists the quantity of insulin dispensed over the years.

patients throughout the analyzed period. The municipality of João Pessoa accounted for the largest proportion of patients, representing approximately 25% to 27% of the total number of records, followed by Campina Grande, with a share of around 10% to 13%. The municipalities of Sousa, Cajazeiras, and Patos showed lower but stable percentages, with no significant variations over the evaluation period, indicating a relatively homogeneous territorial distribution pattern outside the major urban centers.

Figure 2 – Annual comparison by type of insulin dispensed



Source: The authors – 2026

Demographic profile – sex and age

Age

Between 2022 and 2025, there was a gradual increase in the average age of long-acting insulin users, rising from 34.25 to 35.43 years. In contrast, the average age of rapid-acting insulin users remained stable throughout the period. The age difference between the groups increased from 1.15 to 2.34 years, suggesting a progressive divergence in demographic profiles and possible age-based therapeutic stratification.

Gender

Over the period from 2022 to 2025, a stable distribution of users by sex was observed, with a slight predominance of females among both long-acting and rapid-acting insulin users. The proportion of women remained close to 52% in all years analyzed, with no significant variations over time or between insulin types.

Geographic Distribution

A highly consistent geographic pattern was observed in the distribution of

Profile of Insulin Therapy Use in 2025

After cross-referencing the databases using the National Health Card (CNS) as a unique identifier, 3,304 unique patients were identified in the year 2025. Most users (72.1%) were using a combination of long-acting insulin (**glargine**) and rapid-acting insulin (**lispro**), characterizing a basal-bolus treatment regimen. A smaller proportion, 18.9% of patients, used rapid-acting insulin exclusively, while 8.8% used only long-acting insulin, as shown in the following table:

Table 1 – Stratification of users by insulin regimen

User group (2025)	Number of patients
They use only glargine	291
Use only lispro	629
Use glargine + lispro	2,384
Total unique patients	3,304

Table 1: Prepared by the authors—2026

Mean age by treatment group

Analysis of the mean age by treatment group revealed marked differences among the insulin therapy regimens. Patients who used only insulin glargine had the highest mean age, at 57.24 years. In comparison, patients who used only insulin lispro had a mean age of 31.44 years, while those using a combination of insulin glargine and lispro had a mean age of

33.53 years.

Anthropometric Profile by Treatment Regimen

The distribution of body mass index (BMI) classifications varied according to the insulin type. Among those using only insulin glargine, a higher proportion of individuals were overweight (36.43%) and obese (15.46%) compared to the other

groups, in addition to a lower frequency of normal weight (40.55%).

Among patients using only insulin lispro, a normal BMI was the most

common classification (51.51%), with a lower prevalence of overweight (23.85%) and obesity (8.11%), although a higher proportion of un-

derweight patients (15.26%) was observed compared to the group using only glargine.

Table 2 – BMI Classification by Insulin Regimen (%)

BMI Classification	Glargine only % (n = 291)	Lispro only % (n = 629)	Glargine + lispro % (n = 2.384)
Underweight	7.22	15.26	18.58
Normal	40.55	51.51	52.68
Overweight	36.43	23.85	21.14
Obesity	15.46	8.11	6.46
Severe obesity	0.34	1.27	1.13

Table 2: Prepared by the authors – 2026

Figure 1 – Percentage distribution of body mass index (BMI) categories by treatment group among insulin users

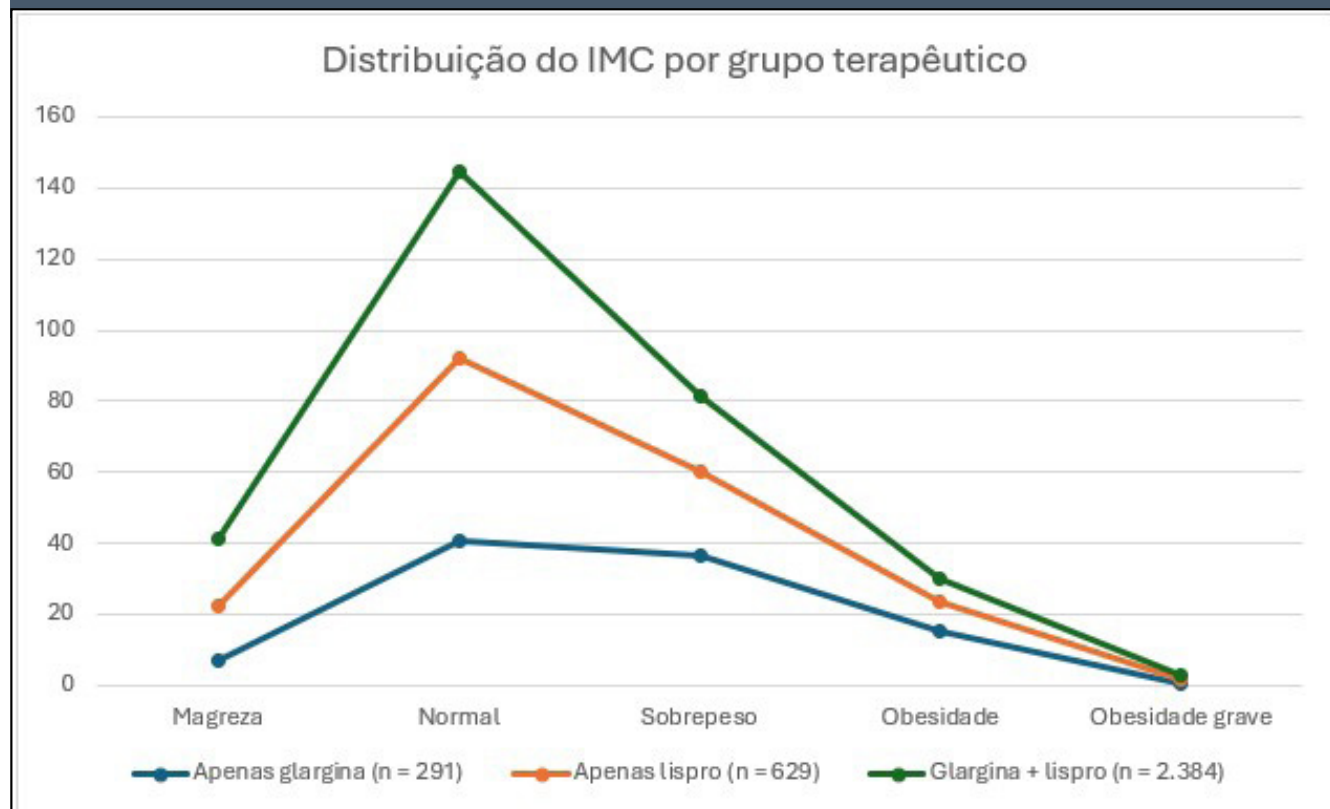


Figure 1: Prepared by the authors - 2026

Similarly, users on a combination regimen of insulin glargine and lispro predominantly had a normal BMI (52.68%), associated with lower percentages of overweight (21.14%) and obesity (6.46%), but with the highest proportion of underweight individu-

als among the groups (18.58%). Severe obesity was rare in all treatment groups, ranging from 0.34% to 1.27%.

DISCUSSION

This study described the epidemi-

ological and therapeutic profile of patients with type 1 diabetes mellitus using insulin analogs who were treated by the Specialized Pharmaceutical Care Component (CEAF) in the state of Paraíba between 2022 and 2025, highlighting relevant trends

from both a clinical and a diabetes care management perspective within the SUS.

The results of this study demonstrate a continuous and consistent increase in the dispensing of insulin analogs between 2022 and 2025, with a more significant increase in long-acting analogs compared to rapid-acting ones. During the period analyzed, the dispensing of basal insulins nearly doubled (a 102.8% increase), while rapid-acting insulins showed a more moderate increase (48.3%), indicating a gradual shift in the therapeutic profile adopted. It is worth noting that, in the state of Paraíba, access to rapid- and long-acting insulin analogs had already been made available and institutionalized since 2007, preceding the national incorporation of these technologies by CONITEC, which occurred later in 2017 and 2019, respectively. This pioneering context may have contributed to the consolidation and expansion of the use of these medications within the Paraíba SUS. This growth is consistent with trends observed in the Brazilian public health system. Studies based on government procurement data indicate a gradual increase in the procurement of insulin analogs following their incorporation into the SUS, especially after the publication of the Clinical Protocol and Therapeutic Guidelines for type 1 diabetes mellitus and the centralization of procurement by the Ministry of Health. This trend reflects both the expansion of access and the consolidation of these technologies in the clinical management of the disease in Brazil^{11,12}

The observed pattern is consistent with the international literature, which points to sustained growth in the use of insulin analogs in low- and middle-income countries, associated with lower glycemic variability, a reduction in hypoglycemia, and greater therapeutic convenience. From the

perspective of pharmaceutical care management, this trend has significant implications due to the budgetary impact of these technologies, reinforcing the importance of monitoring dispensing within the CEAf framework.¹³

The observed demographic findings—with a mean age of around 35 years—are consistent with recent global estimates published by Gregory et al. (2022). The study indicates that the majority of people living with T1D worldwide (64%) are adults between the ages of 20 and 59. Thus, the continued growth in prescriptions at CEAf between 2022 and 2025 reflects not only the prevalence of childhood diagnoses as patients reach adulthood but also the need to sustain care for a young, economically active adult population with increased life expectancy due to access to health technologies. The results of this study revealed a stable distribution of users by sex over the period from 2022 to 2025, with a slight predominance of women ($\approx 52\%$) among users of both long-acting and rapid-acting insulin analogs, with no significant variations between years or between insulin types. These findings are consistent with national population-based epidemiological data, including surveys from VIGITEL—Surveillance of Risk and Protective Factors for Chronic Diseases via Telephone Survey. In the 2023 VIGITEL report, the self-reported prevalence of a medical diagnosis of diabetes among adults in João Pessoa, Paraíba, was very similar between men and women: 7.2% overall, with estimates of 7.2% (4.0–10.3) among men and 7.3% (5.1–9.6) among women in the same year, indicating no marked discrepancy by sex in the occurrence of diabetes in this population^{4,14}.

A stable geographic pattern was observed between 2022 and 2025, with a concentration of users in João Pessoa (≈ 25 –27%) and Campina Grande

(≈ 10 –13%) and lower but consistent percentages in municipalities such as Sousa, Cajazeiras, and Patos, reflecting structural factors such as higher population density, the availability of specialized services, and referral flows to centers with higher levels of care. This finding is consistent with studies on CEAf in Brazil, which indicate that medications with high financial impact tend to be concentrated in centers with more robust clinical and logistical infrastructure. Furthermore, regional inequalities related to socioeconomic conditions, municipal administrative capacity, and healthcare coverage may influence diagnosis, referral, and treatment continuity, explaining the persistently lower rates in smaller municipalities—possibly associated with barriers to access or underdiagnosis^{15,16}.

In 2025, the majority of insulin users in the state (72.1%) were following a *basal-bolus* treatment regimen, combining long-acting analogs (glargine) with rapid-acting analogs (lispro). A smaller proportion used only rapid-acting insulin (18.9%) or only long-acting insulin (8.8%). These findings show significant alignment with the regional picture: while Cavalcante et al. (2020) found that, as early as 2017, 38% of CEAf users in the state of Piauí were using the combination of glargine and aspart, the current data from Paraíba reinforce this trend, with 2,384 patients using the glargine and lispro regimen (Table 3). Additionally, the predominance of females (55%) and the adult age group (20–59 years) corroborates the epidemiological profile found by those authors, who reported 56.4% women and a majority of young adults. This systematic preference for long-acting and ultra-rapid-acting analogs, regardless of variations among specific drugs, reflects the standardization of clinical protocols aimed at mimicking the physiological profile

of the pancreas and enhancing safety against hypoglycemic events¹⁷.

International and national diabetes treatment guidelines emphasize that, in individuals with type 1 diabetes and in many cases of insulin-dependent type 2 diabetes, regimens involving multiple daily doses distributed as basal insulin to cover the fasting state and rapid-acting insulin to cover meals represent the gold standard of care because they allow for fine-tuning of blood glucose levels and a reduction in episodes of postprandial hyperglycemia and hypoglycemia nighttime. The observation that a higher proportion of elderly patients are on a basal-only regimen is supported by the literature: clinical guidelines and reviews recommend long-acting basal insulin to simplify treatment in the elderly due to the lower risk of hypoglycemia and the convenience of less intensive regimens. In addition, the subpopulation with LADA (Latent Autoimmune Diabetes in Adults), frequently identified in adults and sometimes in older patients, tends to progress to insulin use, which explains age-related variations in prescribed regimens. At the same time, studies on the evolution of insulin therapies describe a consistent shift from human insulins to analogs (for clinical reasons), which reinforces the predominance of basal analogs (e.g., glargine) among older adults on simplified treatment^{18,19,20}.

The findings of this study, which show a higher prevalence of overweight and obesity among users of insulin glargine, are consistent with recent literature describing the emergence of obesity in people with type 1 diabetes. A review published in the *International Journal of Obesity* in 2024 demonstrates that the classic notion of type 1 diabetes being limited to lean individuals is no longer valid, as data from international registries indicate a combined prevalence of overweight and obesity ranging

from approximately 15% to 36% in populations with type 1 diabetes, including adults. These percentages are consistent with the values observed in the present study, reinforcing the epidemiological plausibility of the results. The increased prevalence of overweight and obesity among people with type 1 diabetes mellitus has been described as an emerging phenomenon in the international literature, often associated with the concept of “double diabetes,” characterized by the coexistence of metabolic features of type 1 diabetes and the insulin resistance typical of type 2 diabetes. This phenomenon reflects changes in dietary patterns, a sedentary lifestyle, and increased life expectancy among individuals with type 1 diabetes. In this context, the identification of significant proportions of overweight individuals in the study population reinforces the need for care strategies that integrate insulin therapy management with interventions aimed at promoting healthy habits and preventing cardiovascular risk²¹.

However, it is important to note that obesity is not defined exclusively by body mass index (BMI). The literature acknowledges that BMI has limitations because it does not distinguish between fat mass and lean mass, nor does it adequately reflect body fat distribution. Thus, other metrics have been widely used to characterize obesity and cardiometabolic risk, such as waist circumference, waist-to-hip ratio, body fat percentage, and indicators of central or visceral obesity, which are considered particularly relevant in individuals with type 1 diabetes due to their association with cardiovascular risk. Furthermore, environmental factors, lifestyle changes, and increased life expectancy associated with prolonged insulin use contribute to weight gain in this population, which may influence both the anthropometric profile and the choice of treatment regimen. Thus,

the BMI profile identified according to the insulin therapy regimen should be interpreted in light of these multiple dimensions of obesity, in line with the global trends described in contemporary studies^{22–25}.

CONCLUSION

This study characterized the epidemiological, geographic, and therapeutic profile of patients with type 1 diabetes mellitus using insulin analogs who were served by the Specialized Pharmaceutical Care Component in the state of Paraíba between 2022 and 2025. The findings show sustained growth in the dispensing of these medications, especially long-acting formulations, reflecting the consolidation of treatment regimens aligned with current clinical guidelines and the needs of a predominantly young-adult population. The predominance of the basal-bolus regimen, the stability of distribution by sex, and the concentration of users in major urban centers indicate consistency between the disease's epidemiological profile and the organization of the healthcare network within the SUS. Additionally, the significant prevalence of overweight and obesity among people with T1D highlights changes in the anthropometric profile of this population and reinforces the need for clinical approaches that take a comprehensive view of cardiometabolic risk. Taken together, the results provide insights for planning pharmaceutical care and monitoring the use of these therapies within the CEAF, contributing to the improvement of strategies for planning, procurement, and managing the budgetary impact of insulin analogs in the SUS.

This study has some limitations that should be considered when interpreting the results. First, this analysis is based on administrative and secondary data from the CEAF, which depend on the quality of data record-

ing and are subject to incompleteness, inconsistencies, or data entry errors, especially in clinical and anthropometric variables. Furthermore, while the use of the National Health Card as a unique identifier reduces duplications, it does not entirely eliminate

the possibility of inconsistent records in cases of changes to patient information or failures in linking between databases. Finally, since this analysis is limited to the state of Paraíba, the results may not be directly generalizable to other states, which have dif-

ferent socioeconomic, organizational, and health-service-delivery contexts. Nevertheless, the findings provide relevant evidence for the planning and management of pharmaceutical care within the SUS, especially in similar contexts.

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Funding

None.

Declaration of Conflict of Interest and Declaration of Data Availability.

Conflict of interest: The authors declare that there is no conflict of interest.

Data availability: The data supporting the results of this study are available upon request to the corresponding author.